EXHIBIT D

Gynecare

PROLIFT*

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

System til total reparation af bækkenbund
System til anterior reparation af bækkenbund
System til posterior reparation af bækkenbund

Systeem voor reparatie van de gehele bekkenbodem
Systeem voor reparatie van de anterieure bekkenbodem
Systeem voor reparatie van de posterieure bekkenbodem

Totaali lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Système pour cure de prolapsus total
Système pour cure de prolapsus antérieur
Système pour cure de prolapsus postérieur

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

Manufactured for:
GYNECARE WORLDWIDE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

EC
Legal Manufacturer
ETHICON, Sàrl
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CH-2000 Neuchâtel
Switzerland

P19070/B

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PROLIFT*

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT* Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training.

Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair Systems for further information on the GYNECARE PROLIFT procedures.

INDICATIONS

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

DESCRIPTION

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT Pelvic Floor Repair System Components

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Total Mesh Implant

The Total mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends *(see Figure 1)*.

Anterior Mesh Implant

The Anterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively *(see Figure 1)*.

Posterior Mesh Implant
The Posterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends *(see Figure 1)*.

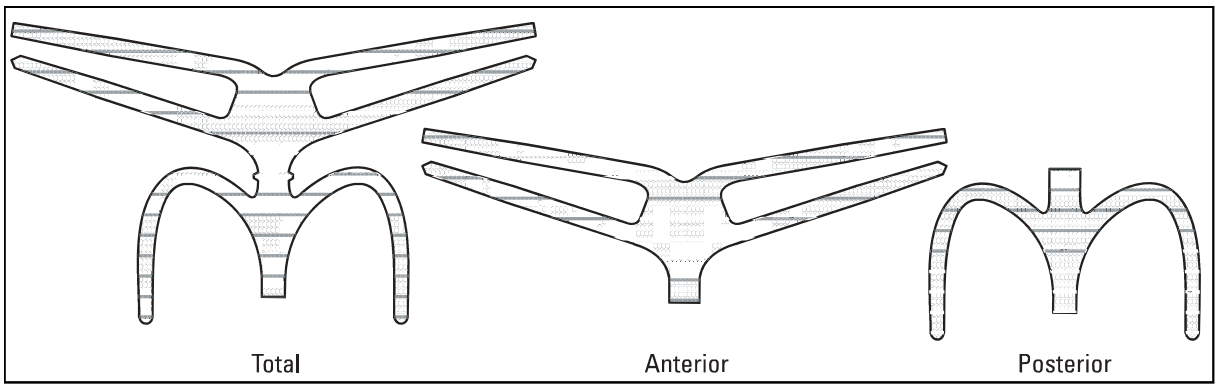

Figure 1 – Mesh Implants (Total, Anterior, and Posterior)

GYNECARE PROLIFT Guide
The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient *(see Figure 2)*.

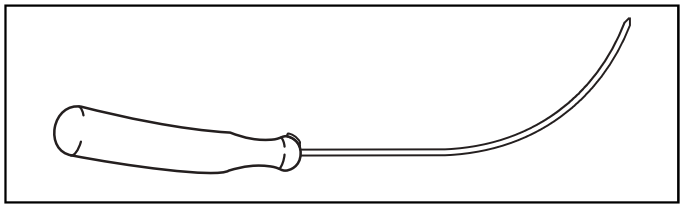

Figure 2 – GYNECARE PROLIFT Guide

GYNECARE PROLIFT Cannula
The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn *(see Figure 3)*.

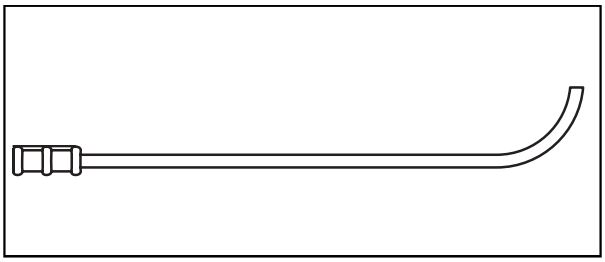

Figure 3 – GYNECARE PROLIFT Cannula

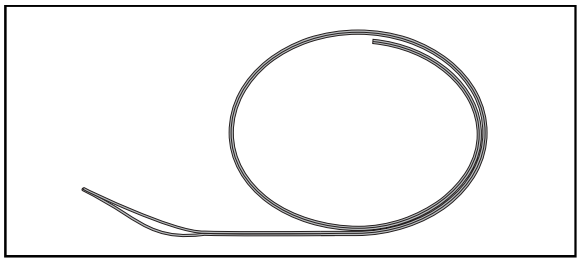

Figure 4 – GYNECARE PROLIFT Retrieval Device

GYNECARE PROLIFT Retrieval Device
The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula *(see Figure 4)*.

INSTRUCTIONS FOR USE

NOTE: All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

Placement of the the GYNECARE PROLIFT Cannula onto the GYNECARE PROLIFT Guide *(See Figures 5A and 5B)*

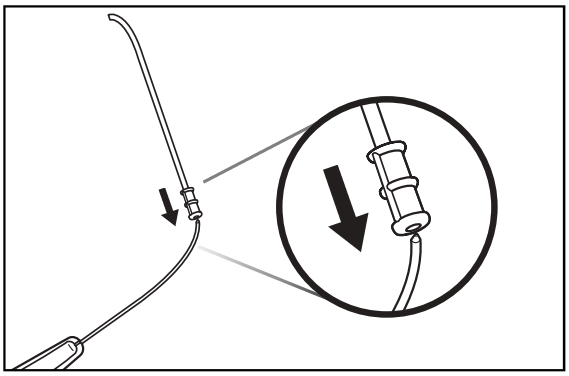

Figure 5A

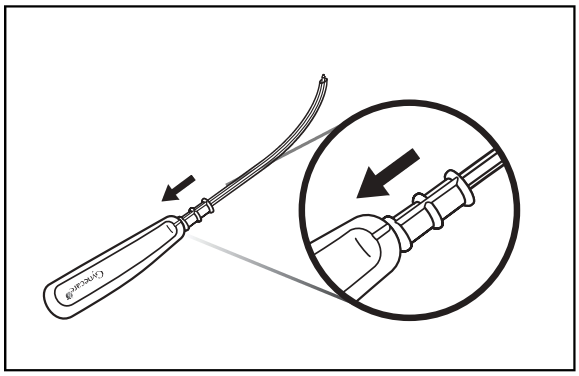

Figure 5B

IMPORTANT: Ensure proper alignment of GYNECARE PROLIFT Cannula and GYNECARE PROLIFT Guide upon assembly as demonstrated in *Figure 5B*.

Placement of the GYNECARE PROLIFT Cannula into the Patient *(See Figures 6A , 6B and 6C)*

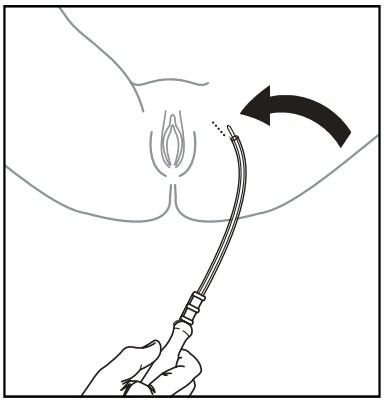

Figure 6A

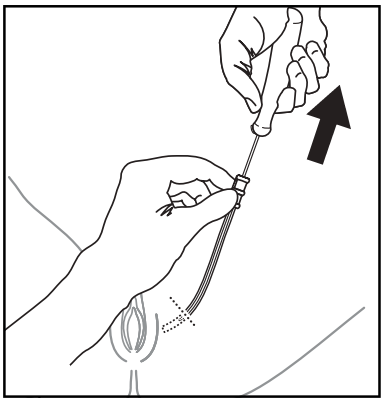

Figure 6B

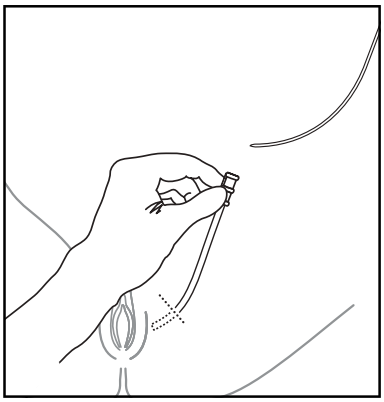

Figure 6C

Insertion and Passage of the GYNECARE PROLIFT Retrieval Device into the GYNECARE PROLIFT Cannula *(See Figures 7A and 7B)*

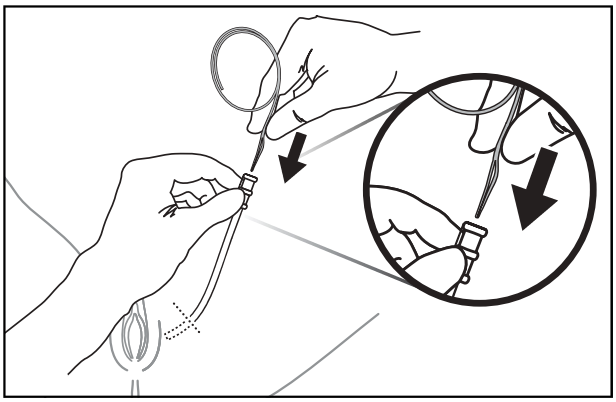

Figure 7A

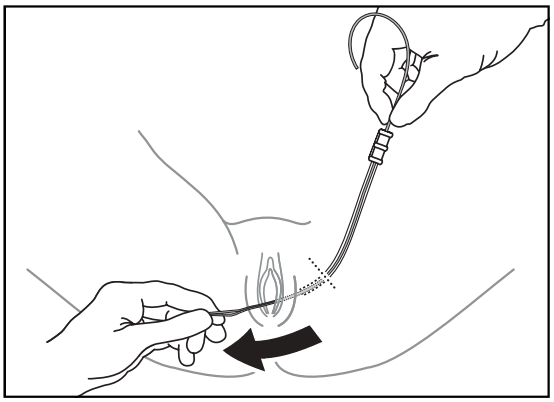

Figure 7B

IMPORTANT: All provided GYNECARE PROLIFT Cannulas and GYNECARE PROLIFT Retrieval Devices should be placed prior to mesh implant installation.

Capture of a Mesh Implant Strap with GYNECARE PROLIFT Retrieval Device ***(See Figures 8A , 8B and 8C)***

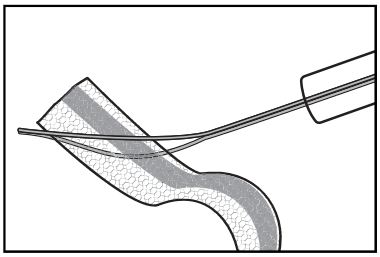

Figure 8A

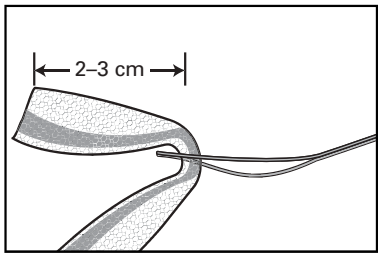

Figure 8B

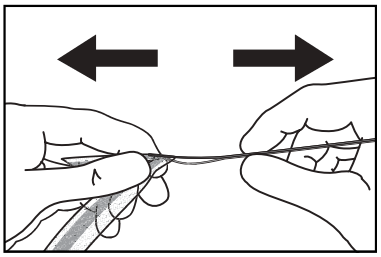

Figure 8C

Passage of a Mesh Implant Strap through the GYNECARE PROLIFT Cannula ***(See Figures 9A , 9B and 9C)***

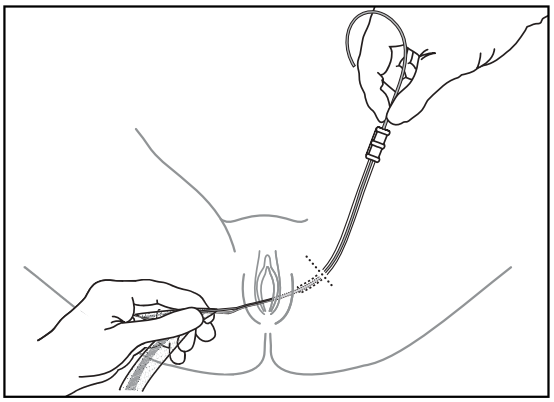

Figure 9A

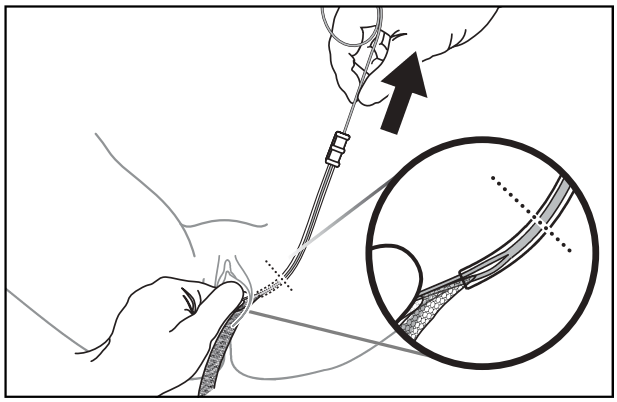

Figure 9B

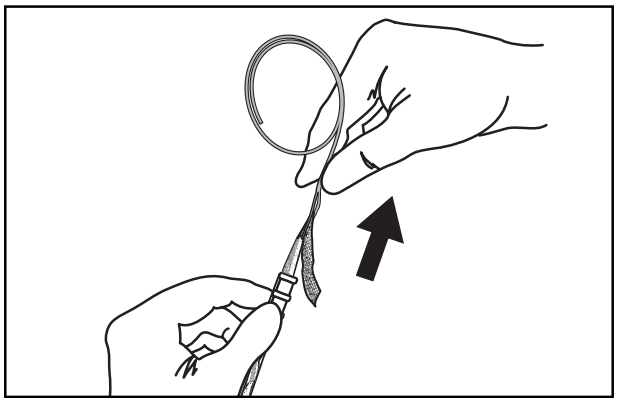

Figure 9C

IMPORTANT: Do not remove the GYNECARE PROLIFT Cannulas from the patient until the mesh implant has been properly positioned.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

PERFORMANCE

Animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

CONTRAINDICATIONS

When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.
- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

STERILITY

The GYNECARE PROLIFT Pelvic Floor Repair Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

Symbols Used on Labeling